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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,895	03/31/2004	Tomoko Takeshita	HIRA.0147	5008
7590 02/03/2006			EXAMINER	
REED SMITH LLP Suite 1400 3110 Fairview Park Drive Falls Church, VA 22042			PARAS JR, PETER	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 02/03/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/812,895

Applicant(s)

TAKESHITA ET AL.

Examiner

Peter Paras, Jr.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/30/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3312004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendments received on 3/31/04 and 6/30/04 have been entered with respect to the claims. Claims 1-9 have been cancelled. New claims 10-15 have been added. Claims 10-15 are pending and are under current consideration.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The preliminary amendment received on 3/31/04 directed entry of the priority claim to 09/666,615 in the first sentence under the section "Background of the Invention" and has not been entered. A proper claim for priority must be in the first line of the specification immediately following the title. Appropriate correction is required.

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Japan on 8/25/2000. It is noted, however, that applicant has not filed a certified copy of the Japanese application as required by 35 U.S.C. 119(b).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: it refers to the specification of 09/666,530 and not the specification of parent application 09/666,615.

Claim Objections

Claims 10-15 are objected to.

Claim 10 is objected to because of the following informalities: the claim refers to a cytoplasm of an injected oocyte. An oocyte is not known to comprise more than one cytoplasm. Appropriate correction is required. Claims 11-12 depend from claim 10.

Claim 13 is objected to because of the following informalities: the claim refers to one kind of mRNA. There are different kinds of RNA molecules that are known such as mRNA, tRNA or rRNA. However, it appears that Applicant intended to recite RNA encoding different polypeptides. Appropriate correction is required. Claims 13-15 depend from claim 13.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is indefinite as written. The claim is indefinite because it does not set forth the relationship between the injected mRNA molecule and the membrane potential. Therefore, it is not understood why the RNA molecule was injected given the plain language of the claims. Claims 14-15 depend from claim 13.

The term "substantially" in claims 10 and 13 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification has failed to provide a definition of what is meant by "substantially" with respect to substantially identical injection depth. It is unclear how identical, substantially identical injection depths may be. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al (5,688,938).

Brown et al taught injection of an mRNA sequence that encodes a parathyroid calcium receptor into the vegetal pole [cytoplasm] of *Xenopus* oocytes. Brown et al taught that the injected oocytes are used for testing the electric response of the oocytes in response to neomycin (which can be interpreted to be a sample); the oocytes can be discriminated upon based their electric response resulting from neomycin treatment. See columns 51-53. The specification has defined injection of mRNA to be at a depth of

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0.02-0.1mm from the cell surface in the context of cytoplasmic injections. See page 9, in lines 25-27. Since Brown et al taught injection of mRNA that encodes a parathyroid calcium receptor into the vegetal pole[cytoplasm] it is inherent that the mRNA was injected at a depth of 0.02-0.1mm, as required by the claims, given the definition provided by the specification with regard to cytoplasmic injection of RNA. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911F.2d 705, 709, 15 USPQZd 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01. Finally, Brown et al taught injection of an oocyte with one injection needle in the same location, the vegetal pole, using the same injection amount per oocyte, about 50nl per oocyte.

Thus, the teachings of Brown et al anticipated all of the instant claim limitations.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

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obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14-16, 18, 21, 24 and 26-27 of U.S. Patent No. 6,593,129. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods as claimed in the '129 patent would result in a plurality of amphibian oocytes in which mRNA has been injected in the cytoplasm. The '129 patent at column 6, in lines 38-41 discussed cytoplasmic injection of mRNA should be at a depth of 0.02-0.1mm. The '129 patent further discussed that a sample can comprise a gene, which can be DNA or RNA. See column 5, at lines 30-36. Finally, the '129 patent at the paragraph bridging columns 9-10 taught that injected oocytes can be used for screening a sample.

Thus, claims 14-16, 18, 21, 24 and 26-27 of U.S. Patent No. 6,593,129 anticipate the instant claims.

Claims 10-12 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,803,207. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods as claimed in the '207 patent would result in a plurality of amphibian oocytes in which mRNA has been injected in the cytoplasm. The '207 patent further discussed that a sample can comprise a gene, which can be DNA or RNA. See column 5, at lines 29-34. The '207 patent at column 9, in lines 25-28 discussed injection of mRNA should be at a depth of 0.02-0.1mm, which is consistent with cytoplasmic injection.

Thus, claims 1-6 of U.S. Patent No. 6,803,207 anticipate claims 10-13 of instant application.

Claims 10-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/774,613. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods as claimed in the '613 application would result in a plurality of amphibian oocytes in which mRNA has been introduced. The claims of the instant application are product by process claims, which are interpreted to read on oocytes comprising mRNA in cytoplasm. The '613 application in the abstract disclosed that RNA encoding a G-protein coupled receptor was

transfected into a *Xenopus* oocyte. It is obvious that during transfection RNA will enter the cytoplasm.

Thus, claims 1-5 of copending Application No. 10/774,613 anticipated claims 10-12 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 10-16 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-16 of copending Application No. 10/876,551. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not patentably distinct from each other because the methods as claimed in the '551 application would result in a plurality of amphibian oocytes in which mRNA has been introduced. Moreover, the claims of the '551 application are directed to methods of screening compounds. The claims of the instant application are product by process claims, which are interpreted to read on oocytes comprising mRNA in cytoplasm. The '551 application in paragraphs 0056-0057 disclosed that RNA may be injected into a amphibian oocyte. In paragraph 0060 the '551 application discussed cytoplasmic injection of mRNA at a depth of 0.02-0.1mm.

Thus, claims 12-16 of copending Application No. 10/876,551 anticipated claims 10-16 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Paras, Jr. whose telephone number is 571-272-4517. The examiner can normally be reached on M-Th, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.

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**PETER PARAS, JR.
PRIMARY EXAMINER**

